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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/015,162	12/11/2001	Aaron Gershon Filler	GJE-18D1	6118

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EXAMINER	
WANG, SHENGJUN	
ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 06/18/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Applicati n No. 10/015,162	Applicant(s) FILLER ET AL.	
	Examiner Shengjun Wang	Art Unit 1617	

-- The MAILING DATE of this communicati n appears on the c ver sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 March 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 4-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 4-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claim Rejections 35 U.S.C. – 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 1, 4-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sierra et al. (US Patent No. 5,290,552, IDS U3) in view of Matsueda et al. (US Patent No. 4,927,916, IDS U1) and Bhargava et al., and further in view of Good

Sierra et al. teach a composition comprising fibrinogen, factor XIII, thrombin, a therapeutic agent such as an antibiotic which may be in the form of particulate. See, column 4, lines 20-26 and lines 63-66 and column 5, lines 48-63. The composition further comprises an antifibrinolytic agent such as amino caproic acid (column 4, lines 50-60) and a growth factor (column 5, lines 7-10). Sierra et al further teach that the composition can serve as a vehicle for a wide variety of components, which may impact desirable physical, chemical, biological and /or therapeutic advantage. See, column 4, lines 63-66 and column 5, lines 48-63.

3. Sierra et al do not teach specifically that the therapeutic agent is a particulate radiotherapeutical agent.

4. However, Matsueda et al. teach an antibody-based particulate radionuclide. See, particularly, column 7, lines 14-59, column 8, lines 7-66. Matsueda et al. further teaches to employ 56 Fe in isotope labeled material. See, particularly, column 9, lines 21-27. Bhargava et al. teach antibody-based radionuclides and their employment as therapeutical agents. See the

abstract. Good teaches that employing various radionuclides (such as Pd-103, Y-90) according the properties (such as half-time, particle, etc.) of the radionuclides is well-known in the art. See, particularly, column 15-40.

Therefore it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed the invention was made, to employ the composition of Sierra et al as a delivery vehicle for the antibody-based radiotherapeutical agent of Bhargava et al. and Matsueda et al., i.e., employing the radiotherapeutical agent of Bhargava et al and Matsueda et al. as the therapeutical agent in the composition of Sierra et al.

A person of ordinary skill in the art would have been motivated to employ the composition of Sierra et al as a delivery vehicle for the antibody-based radiotherapeutical agent of Bhargava et al. and Matsueda et al. because that the composition of Sierra et al is known as a controlled release drug delivery vehicle. It would be reasonably expected to be similarly useful to deliver any known therapeutical agent. Further, employment of the method herein in a well-known therapy, such as brachytherapy or radiation synovectomy, is seen to be obvious since the method is obvious as discussed above. Further, employment of a particular materials well-known to be useful in radiotherapy is seen to be a selection from amongst equally suitable material and as such obvious. Ex parte Winters 11 USPQ 2nd 1387 (at 1388); or a matter of optimization of a result effective parameter, which is considered within the skill of the artisan. See, In re Boesch and Slaney (CCPA) 204 USPQ 215.

Response to the Argument

Applicants' amendments and remarks submitted March 30, 2003 have been fully considered, but are not persuasive for reasons discussed below.

Regarding the remarks that the particles are *immobilized in the glue,* note Sierra et al teach broadly that the composition can serve as a vehicle for a wide variety of components which may impact desirable physical, chemical, biological and /or therapeutic advantage. Therefore, it would have been obvious to employ the composition as a vehicle for a particulate component.

Applicants assert that the claimed methods do not require the release of the immobilized particle before the half-life of the radioactive components, therefore it would not be obvious to employ the composition of Sierra. The arguments are not probative. First, the method as described in the specification is a process of controlled release. It releases the particular until after the half-life time of the radioactive ingredient. Second, Sierra et al teach broadly that the composition can serve as a vehicle for a wide variety of components which may impact desirable physical, chemical, biological and /or therapeutic advantage. Therefore, it would have been obvious to employ the composition as a vehicle for a particulate component. Further, the particles herein are eventually diffused, or absorbed. See the specification, particularly, pages 17-22. It would be prima facie obvious to one of ordinary skill in the art, to employ tissue glue as carrier for the radiotherapeutical agent. Note holding the agent indefinite is a way of *controlled release.*

Applicants further argue that Sierra's patent would not enable the instant invention since Sierra requires therapeutical active substance *must be* released from the adhesive material. This is incorrect. In fact, Sierra teaches various substances, beside releasable active compounds, are suitable to mixed with composition. Examples of such substances including polymers, glasses, metals, ceramics, composites thereof, etc. (column 5, line 14-15).

Applicants argue that Matsueda and Bhargava do not teach expressly the radio therapeutic agent herein, as evidence provided in Good, selection and optimization of particular radiotherapeutical agents is well-known in the art, and is therefor obvious.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shengjun Wang, Ph.D. whose telephone number is (703) 308-4554. The examiner can normally be reached on Monday-Friday from 8:30 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, can be reached on (703) 305-1877. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Examiner

SHENGJUN WANG
PATENT EXAMINER

Shengjun Wang

June 16, 2003